CBI
Ministry of Foreign Affairs

EU legislation on CE-marking: Machinery - Instruction plan -

Summary

This file will guide you through the whole process of CE marking for machinery. This includes a brief update on modifications in legislation. See directive 2006/42/EC. Since this modification is subject to national implementation of the EU member states, this directive will enter into force not later than 29 December 2009. Before then, directive 98/37/EC remains valid.

This guidance is based on the experiences of CBI when assisting exporters in developing countries. So, if you are manufacturing or exporting machinery to the EU, please read this document carefully.

This document outlines the specific issues for *Directive 98/37/EC: Machinery* (MD). For the purpose of this document, the current directive 98/37/EC is described. The modifications in 2006/42/EC are mostly explanatory to avoid common misunderstandings, with a few important changes. See: 2006/42/EC for access to this directive.

➲ *For more information* see the article on the modifications on the machinery directive, click here. From page 8, you will notice texts in red in the left column. These are modifications. In the right column, you will find the explanation. See comparisons on pages 25-98

Steps to apply the CE-marking

Step 1	Determine which Directive(s) are applicable to your product
Step 2	Check which standard(s) are applicable to your product
Step 3	Check if the product complies with the essential health and safety requirements of the Directive(s)
Step 4	Check if a notified body must be involved for certification, contact the notified body for details on the procedures
Step 5	Draw up a Technical File, showing how the product complies with the requirements of the Directives, and which specifications (standards) have been applied
Step 6	Test the product (type) according to the specifications in the technical file, and, if required in the relevant Directive(s), submit a model of the product to an EC type approval by a notified body
Step 7	Draw up an EC Declaration of Conformity
Step 8	Draw up a file in which the production process is described and, if required in the relevant Directive(s), submit the production process to a quality control procedure as describes in the Directive(s)
Step 9	After all conformity assessment procedures: affix the CE-marking to the product
Step 10	Monitor the production process

Step 1 - Determine which Directive(s) are applicable to your product

Find out which Directive applies to your product. This is done by looking at the scope of the Directive, which is described in its text. Please note that more than one Directive might be applicable to your product.

1.1 The Machinery Directive

The Machinery Directive 98/37/EC is renewed and will enter into force not later than 29 December 2009. Before then, former Directive 98/37/EC remains valid. The scope of the Directive is:

- (a) machinery;
- (b) interchangeable equipment;
- (c) safety components;
- (d) lifting accessories;
- (e) chains, ropes and webbing;
- (f) removable mechanical transmission devices;
- (g) partly completed machinery.

For the full text of the Directive, click here. For an EU guidance document on the Machinery Directive, click here.

The Machinery Directive covers machinery and individually marketed safety components of machinery and lays down essential requirements for health and safety mostly concerning operators and persons near machinery. The essential safety requirements do not directly concern environmental protection or the technological performance of machinery. Some of them can obviously help to ensure these. For example, intrinsic reduction of machinery noise for the operator helps to reduce environmental noise.

➲ *Please note* that step 1 requires investigation whether other Directives might be applicable as well. The scope of the Directives reveals if a product is described by the Directive. Some products may be subject to more than one Directive. For example, for electrical machinery the machinery Directive, the Low Voltage Directive (LVD) and the Directive on Electro-Magnetic Compatibility (EMC) are also applicable. If the machinery contains pressure equipment, the Pressure Equipment Directive (PED) may be relevant, and if the machinery is designed for use in a potentially explosive atmosphere, the ATEX Directive requirements must be observed. See the related documents on the various Directives mentioned. To establish the relevance of the other Directives, see step 1 in each of the Directives described.

➲ *Please note* that each definition is known for its exceptions. Thus, the simultaneous application in two different Directives may also be excluded. For example, if the risks of machinery are mainly of electrical origin, e.g. electrical shock, short circuit), the Machinery Directive is not relevant, since the risks are covered by the LVD Directive (and the EMC Directive).

Directives that possibly apply as well

Directive	Title	Abbreviation
2006/95/EC	Low Voltage	LVD
2004/108/EC	Electromagnetic Compatibility	EMC

97/23/EC (as amended)	Pressure Equipment	PED
94/9/EC	Equipment and protective systems intended for use in potentially explosive atmospheres	ATEX

➲ *Please note* that a full list of Directives is shown in the related document CE marking implementation plan. This includes a table with arrows, which are links to websites showing Directives, information about Directives, development of standards, and a list of harmonised standards in relation to the Directive concerned.

1.2 Definitions of Directive 98/37/EC , article 1 (2) and 2006/42/EC "Machinery", article 2.

1.3 Scope of the Directive

For a good understanding of Directive 98/37/EC: Machinery you should have a look at the Directive itself. You can find the complete text on the internet on the website of the European Union, click here for a complete overview of the chapters and annexes of Directive 98/37/EC: Machinery. Article 1 of the Directive describes the scope of the Directive. The following terms are highlighted:

An assembly of parts. This excludes basic components. However, certain basic components such as items of lifting gear (hooks, rings, rings with stud connections) are covered (although not actually safety components or machines, these products are implicitly covered by the Directive).

The parts must be linked. This does not exclude machinery which is sold dismantled for ease of transport or in kit form, as the manufacturer is obliged to design his machinery in accordance with the Directive. In these special cases the manufacturer gives the necessary assembly instructions to the customer. CE marking obviously relates only to the actual design of the product and the assembly instructions. Assembly itself is the user's responsibility. The manufacturer is not responsible for any failure to follow the assembly instructions he has provided. Confirmation of this can be found in essential requirements 1.1.2(a), 1.5.4, 1.7.4(a) and 3.6.3(b) mentioned in Annex I of the Machinery Directive.

One of the parts must move. This movement must result from external energy (electricity, battery, fuel, etc.) or stored energy (spring, weight). Thus, by way of exception from this rule, the Machinery Directive also covers certain lifting equipment moved directly by manual effort. Other machinery moved by manual effort directly is excluded. Static assemblies (shelving, scaffolding, pallets, hand tools, hand-pushed trolleys, etc.) are therefore excluded.

For a specific application. This implies that machinery which is unfinished, to the extent that it cannot function, is not covered by the Directive. This is confirmed by Article 4(2) of the Directive. The list of applications given here is not exhaustive: the phrase "in particular" means that these are merely examples. However, the concept of "application" implies that machinery is marketed for actual use by an operator.

Assembly of machines, complex installation. The term "machinery" also covers an assembly of machines, a complex installation or partly completed machinery. A "complex installation" means an assembly of machinery, appliances and mechanisms which, in order to contribute to the same result, generally the same production, are arranged and installed so as to be interdependent in operation. In other words, if complex installations such as

production lines and special machinery made up of several machines form a coherent whole; they are covered by the Directive.

Interchangeable equipment. The concept of machinery extends to "interchangeable equipment" modifying the basic function of a machine or providing a new function. This often consists of a basic machine (e.g. a tractor) to which a wide variety of equipment can be attached to transform it into a ploughing, harvesting, excavating, lifting or loading/unloading machine, etc. Such equipment is often purchased long after the basic machine and from a different supplier. In order to avoid divergent design principles and safety standards of machinery and interchangeable equipment, the latter are subject to the Machinery Directive.
Interchangeable equipment consists of parts that are related to the basic functions. Spare parts are not regarded as interchangeable equipment. For example, a new tyre for the tractor is a spare part, not interchangeable equipment. It does not change the function of the machine, nor the risks.

Safety component. A "safety component" is a component that does not make a direct or main contribution to machinery's "defined use". The safety function is the specific characteristic of a safety component. This safety function is secondary to the machinery's main function. For this reason, a subassembly of machinery within the meaning of Article 4(2) cannot be classified as a safety component. Neither can a safety component be a complete machine or interchangeable equipment within the meaning of Article 1(2) of the Directive.
The safety component concept is objective and unquestionable for a number of components, and in this case the manufacturer has no choice in the matter. For a list of safety components, see directive 2006/42/EC, Annex V.

For other components, the question is more delicate because their legal status will depend on the function that the manufacturer intends to give them. In this case, he will choose whether to declare them as "safety components". Thus a limit switch can be used for the normal operation of the equipment. It is not a safety component. The same limit switch with a safety function only could be described as a "safety component". There are no great difficulties in making the distinction.

➲ *Excluded* are components having a functional role. The main purpose of "functional components", is *not* safety-related. A direct safety function is one where a malfunction would increase the risk of injury or health risks. This obviously does not mean that these "functional" components may be unsafe or unreliable, only that they are not covered by the Machinery Directive. It is for the machinery manufacturer who acquires components for incorporating into machinery to avoid the failure of the component affecting the whole machine.

1.4 Exclusions from the scope of the Machinery Directive

The following types of machinery are *excluded* from the scope of the Directive. The following list is illustrative, the exact list can be found in Article 1(3) (click here for the whole text of Article 1). Please note that for *below-mentioned* products other Directives are valid, see the following paragraph 1.5 and 1.6.

Exclusions from the scope of the Directive:
- Machinery whose only power source is directly applied manual effort, unless it is a machine used for lifting or lowering loads,
- Medical devices,

- Special equipment for use in fairgrounds and/or amusement parks,
- Steam boilers, tanks and pressure vessels,
- Machinery specially designed or put into service for nuclear purposes,
- Radioactive sources forming part of a machine,
- Firearms,
- Storage tanks and pipelines for petrol, diesel fuel, inflammable liquids and dangerous substances,
- Cableways, including funicular railways, for transportation of persons,
- Agricultural and forestry tractors, as defined in Article 1(1) of Directive 74/150/EEC.
- Machines specially designed and constructed for military or police purposes,
- Means of transport of persons using rack and pinion rail mounted vehicles,
- Mine winding gear,
- Theatre elevators,
- Construction site hoists intended for lifting persons or persons and goods.

Please note that the exclusions are somewhat different in Directive 2006/42/EC.

1.5 Other Directives that should be consulted: Article 1(4)

Article 1(4) of the Machinery Directive states:
"Where, for machinery or safety components, the risks referred to in this Directive are wholly or partly covered by specific Community Directives, this Directive shall not apply, or shall cease to apply, in the case of such machinery or safety components and of such risks on the implementation of these specific Directives."

There are specific Directives covering mainly electromagnetic phenomena, potentially explosive atmospheres, and the Directive on the sound power level of concrete-breakers and drills. The Machinery Directive therefore does not apply in the case of the hazard covered by a more specific Directive.

It is possible for the specific Directive to lay down a more stringent certification procedure. In this case, such procedures must be limited to the hazard covered by the specific Directive and must not concern the other hazards referred to in Annex I to this Directive. The scope of a Directive is limited to the hazards covered.

A risk assessment will reveal whether the risks are "Mainly" of electrical origin. If there are risks both from electrical and other (mechanical, chemical, etc.) origin, both Directives apply.

1.6 Other Directives that should be consulted: Article 1(5)

In Article 1(5) the Machinery Directive states:

"Where, for machinery, the risks are mainly of electrical origin, such machinery shall be covered exclusively by Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits."

If the risks involved are mainly from electrical origin, then Directive 73/23/EEC: Low Voltage applies. There are two possibilities:

- Certain types of electrical equipment, also regarded as machinery, are *completely excluded* from the scope of the Machinery Directive, in line with Article 1(3) of the Machinery Directive, which gives a list of product groups that are excluded, see

the above mentioned list in paragraph 1.4 of this document.

In order to determine whether exclusion from the scope of the Machinery Directive is valid and the Low Voltage Directive will apply, the manufacturer must analyse the hazards presented by that product. Because, the Machinery Directive states that a product with mainly *electrical risks* will fall under the Low Voltage Directive.

The principles that can be used to evaluate risks are set out in the International Standards EN-ISO 12100-1 "Safety of machinery - Basic concepts, general principles for design - Part 1: Basic terminology, methodology", EN-ISO 12100-2 "Safety of machinery - Basic concepts, general principles for design - Part 2: Technical principles" and EN-ISO 14121-1 "Safety of machinery - Risk assessment - Part 1: Principles".

In addition, a useful document is ISO/TR 14121-2 "Safety of machinery - Risk assessment - Part 2: Practical guidance and examples of methods"

Where the manufacturer's assessment shows that hazards are linked primarily to an electrical failure, the equipment is deemed to be exclusively in compliance with the Low Voltage Directive. This Directive includes all aspects of safety. Not only electrical but machine safety as well.

In the new Machinery Directive, clarity is given about the equipment covered by the Low Voltage Directive only:

— electrical and electronic products falling within the following areas, insofar as they are covered by the Low Voltage Directive:
— household appliances intended for domestic use,
— audio and video equipment,
— information technology equipment,
— ordinary office machinery,
— low-voltage switchgear and control gear,
— electric motors.

- All electric machines activated at between 50 and 1000 volts in alternating current and between 75 and 1500 volts in direct current fall within the scope of both the Machinery Directive and the Low Voltage Directive, the latter applying additionally for electrical hazards. Please note that the machines cited in Article 1(5) of the Machinery Directive are excluded.

The following points apply to electrically-operated machinery within the voltage limits laid down by the Low Voltage Directive.

- The requirements of the Low Voltage Directive concerning electrical hazards must be met.
- For all such machinery, including machinery falling within the scope of Annex IV to the Machinery Directive, the conformity assessment procedures specified in Article 8 of the Machinery Directive are applicable to all hazards.

Step 2 - Check which standard(s) are applicable to your product

For compliance with the Directives that apply to your product, standards give detailed technical information on implementing the EU requirements. However, not all standards have been harmonised yet. Only standards that have their reference published in the Official Journal of the EU are called 'harmonised standards'. Complying with these standards means that the authorities presume compliance with the Directives. This step of checking the relevant standards – whether or not harmonised – is crucial for CE-marking.

2.1 Types of standards

Standards give detailed technical information on implementing the EU requirements. It is up to the manufacturer to choose how to implement the requirements, since the New Approach Directives are based on a voluntary use of standards for filling in the technical details. There are several types of standards:

- ***Fundamental safety standards (A)***

Type A standards cover fundamental safety standards, supply basic definitions, design principles etc. They are used for all types of machinery. Examples of these are EN-ISO 12100-1, EN-ISO 12100-2.and EN-ISO 14121-1.

- ***Generic safety ergonomic aspects* (B)**

Type B standards deal with generic safety ergonomic aspects, or with safety devices for a group of machinery. Examples are EN 418, EN 294, EN 349, and EN 60204-1.

- ***Specific categories of products* (C)**

Type C standards are used to deal with specific categories of products. They describe the specific demands in a certain category whilst referring to the relevant type A and B standards for the generic requirements. Examples of C type standards are those for pumps, cranes, industrial trucks, packaging machinery, elevators etc.

The EU is in the process of harmonising the standards that are used in all the individual EU countries. It is recommended to look for the applicable C type standard(s) in the first place, since these refer to the applicable A and B type standards for more general requirements. The specific risks are highlighted in this type of standard. If no relevant C type standards or draft standards are available or suitable, the A and B type standards can be applied to comply to the requirements of the Directives (step 3).

2.2 How to find harmonised standards

The following list gives an overview of *harmonized standards*. Please note that although the list is updated regularly, it may not be complete. All newly harmonized standards are published in the Official Journal of the EU.

2.3 Other standards and draft standards

Many more standards are under development. At the website of CEN you can look up standards and their status (e.g. ratified, under approval, see `Reference list`).

In Annex B a list of machinery safety issues to be dealt with in type A and type B standards had been given (↓ EU standards).

Step 3 - Check if the product complies with the essential health and safety requirements of the Directive

Apply the relevant standards for the performance requirements in the Directives or the technical verification, and, where appropriate, a risk assessment.

Check the essential health and safety requirements of the Machinery Directive. The requirements are as well given within the Directive in Annex I. The text of the essential

requirements is available on the internet, including comments. Click here for the overview of requirements, and click further to read the comments.

The EU designed flow charts for all Directives with the process of the so-called "conformity assessment". You can find the flow chart for machinery in Annex A of this document (*Click* ↓ Flow Chart). It is recommended to print this flow chart.

Please note that the new Machinery Directive involves a number of changes.

Most notorious are:
- more explanation of the risk assessment
- more basic definitions
- more elaborate requirements on ergonomics and operating and control positions
- operational and emergency stop functions
- guards, intermovable and interlocking
- bench mark required for noise and vibration
- larger section on instructions, with a special annex (VI) for the assembly of unfinished machinery
- new section on portable fixing and other impact machinery

Step 4 - Check if a notified body must be involved for certification

Contact the notified body for details on the procedures.

It depends on the Directive(s) involved if a notified body must be involved for certification of the product and the production process. This is required for machinery, described in Annex IV of the Directive. For a list of notified bodies, click here.

➲ *Note that*:
- The Low Voltage Directive usually applies as well, and a notified body can be involved on a voluntary basis. For a competent body (EMC Directive) the same step applies.
- 10 practical tips on how to select a notified body are given in the related document explaining the step by step approach followed in this document, i.e. the CE marking implementation plan.

Link to notified bodies for the present Machinery Directive 98/37/EC
Link to notified bodies for the new machinery Directive 2006/45/EC

Step 5 - Draw up a Technical File, showing how the product complies with the requirements of the Directives, and which specifications (standards) have been applied

The technical file should contain the documentation on how the conformity has been achieved. If the Directive requires a verification of the file, for example when the product has to be submitted to an EC type approval, this file will be checked together with the product or separately. Besides general information like name and address of the manufacturer, identification of the product, drawings and overviews of the product, all relevant detailed information on the design, construction and testing, risk assessment, certificates, applied standards, a description of the preventive measures and a copy of the user manual must be included.

The technical file is described in the section on the Declaration of Conformity in Annex V of the Directive (clause 3a), comprising:

- An overall drawing of the machinery together with drawings of the control circuits,
- Full detailed drawings, accompanied by any calculation notes, test results, etc., required to check the conformity of the machinery with the essential health and safety requirements,
- A list of:
    - the essential requirements of this Directive,
    - standards and other technical specifications, which were used when the machinery was designed,
    - a description of methods adopted to eliminate hazards presented by the machinery,
    - if the manufacturer so desires, any technical report or certificate obtained from a competent body or laboratory [(1)],
    - if he declares conformity with a harmonised standard which provides therefore any technical report giving the results of tests carried out at his choice either by himself or by a competent body or laboratory [(1)],
    - a copy of the instructions for the machinery.

[(1)] A body or laboratory is presumed competent if it meets the assessment criteria laid down in the relevant harmonised standards.

Since machinery is usually manufactured in series, there are additional requirements concerning the production process (Annex V, clause 3b), the technical file also contains the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of the Directive.

The manufacturer must carry out necessary research or tests on components, fittings or the completed machine to determine whether by its design or construction, the machine is capable of being erected and put into service safely.

Failure to present the documentation in response to a duly substantiated request by the competent national authorities may constitute sufficient grounds for doubting the presumption of conformity with the requirements of the Directive.

Step 6 – Test the product (type) according to the specifications in the technical file, and, if required in the relevant Directive(s), submit a model of the product to an EC type approval by a notified body

All testing carried out by the manufacturer, a laboratory, test house or notified body, will be included in the technical file. Since it is not always possible or feasible to test onsite, the technical file may be completed as far as the description of the product and the (intended) compliance with the relevant Directives and standards.

Most types of machinery may be submitted to all necessary testing by the manufacturer himself or his authorized representative in the EU. Roughly, this covers 95% of all machinery. However, some machinery must be submitted to an EC-type approval. In the Machinery Directive you will find this laid down in art. 8 (a) of Article 8 and in Annex IV. In Annex IV you will find all types of machinery and safety components for which the procedure referred to in Article 8(2)(b) and (c) must be applied.

The submission of the product to the EC-type approval is the procedure that the product (type) is tested and certified. This is described in the section on EC type Examination in Annex VI of Directive 98/37/EC. A prototype of the product, or a range if various types are tested at the same time, is sent to a notified body. For other types of machinery an EC type approval is not required.

➲ *Please note* that a notified body for one Directive is not automatically notified for another Directive. In the case of the machinery Directive, a body can be notified only for machinery listed in Annex IV, and the list is very short. A notified body for the Machinery Directive will not examine the specific hazards (explosion, electromagnetism, noise, pressure) that a notified body for other specific Directives would examine (such as on electromagnetic phenomena, potentially explosive atmospheres and sound power levels).

Step 7 – Draw up an EC Declaration of Conformity

With the EC Declaration of Conformity, the manufacturer officially declares that the product complies with essential requirement of the applicable Directives. The manufacturer also declares that, if this product has been submitted to an EC type approval, each product is in conformity with the model that has been approved.

Again, it is wise to consult the internet. Several Annexes of the Machinery Directive give precise information on how you should provide the information.

➲ Please have a look at the following links:

- Annex II: Contents of the declaration of conformity
- Annex V: EC declaration of conformity (when the machinery or safety component is not listed submitted in Annex IV and submitted to a notified body)
- Annex VI: EC Type examination (when the machinery or safety component is listed submitted in Annex IV and submitted to a notified body).

Step 8 – Draw up a file in which the production process is described, and, if required in the relevant Directive(s), submit the production process to a quality control procedure as describes in the Directive(s)

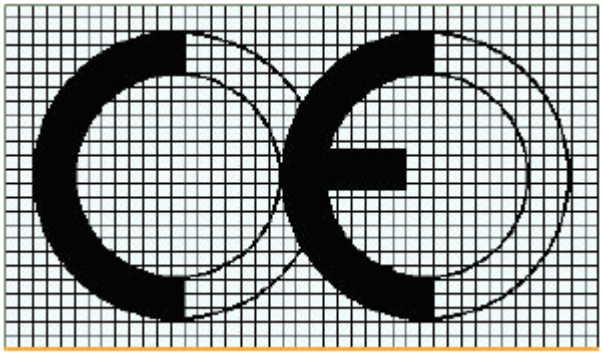
To ensure that each product will be the same as the model that has been approved, the production process must be described. For many Directives, this is an obligation.

An important issue regarding the users manual is liability. See Annex V, clause 3(b) in the Machinery Directive 98/37/EC. A manufacturer cannot pass on liability to the manufacturer of a part or component. The choice of these must therefore be justified in the file, insofar as they have a bearing on compliance with one or more requirements.

Step 9 - Affix the CE marking

Finally, the CE marking has to be affixed to the product. It must be clearly readable and irremovable attached to the product. Besides the CE marking, the name and address, serial or type indication, as well as the production year of the product have to be mentioned on the product.

The CE conformity marking shall consist of the initials ‘CE' taking the following form:



- If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.
- The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.

Regarding the CE marking itself, more information can be found in the Machinery Directive at the following link to Annex III.

Step 10 - Monitor the production process, the development of legislation and standards

After affixing the CE marking, make sure that the conformity is maintained.

The declaration of conformity becomes void if alterations to the type are made. Some alterations may be very small. Still, it is important to put these alterations into a file.

New and revised standards do not influence the validity of the CE marking and the EC Declaration of Conformity.

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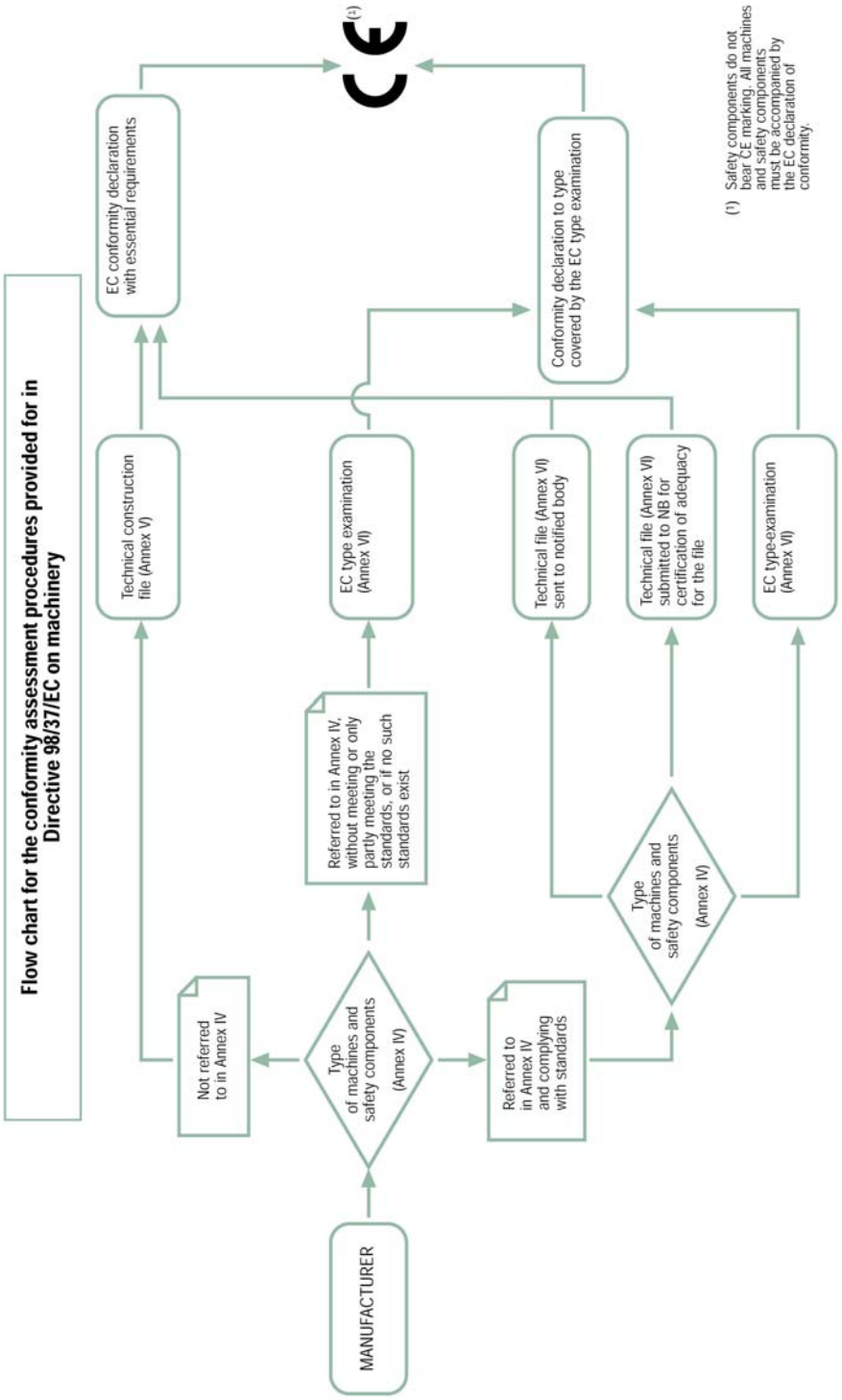
Annex A Flow chart Click **(↑ back to the text)**


Flow chart for the conformity assessment procedures provided for in Directive 98/37/EC on machinery
MANUFACTURER
Type of machines and safety components (Annex IV)
Not referred to in Annex IV
Referred to in Annex IV and complying with standards
Referred to in Annex IV, without meeting or only partly meeting the standards, or if no such standards exist
Type of machines and safety components (Annex IV)
Technical construction file (Annex V)
EC type examination (Annex VI)
Technical file (Annex VI) sent to notified body
Technical file (Annex VI) submitted to NB for certification of adequacy for the file
EC type-examination (Annex VI)
EC conformity declaration with essential requirements
Conformity declaration to type covered by the EC type examination
CE (1)
(1) Safety components do not bear CE marking. All machines and safety components must be accompanied by the EC declaration of conformity

Annex B: Type A and type B standards for machinery safety Click **(↑ back to the text)**

➲ For an explanation on how to use the table after clicking the arrows below, please see the document on the outline of the CE marking implementation plan.

Directive 98/37/EC - Machinery safety (Reference list)	**View Standards**
Acoustics	▶
Ergonomics	▶
Eye protective equipment	▶
Light and lighting	▶
Low-voltage switchgear and control gear including dimensional standardization	▶
Machine tools - Safety	▶
Mechanical vibration and shock	▶
Potentially explosive atmospheres - Explosion prevention and protection	▶
Safety of machinery	▶
Safety of machinery: electro-technical aspects	▶